RECAST OF THE MEDICAL DEVICES DIRECTIVES

PUBLIC CONSULTATION

1. THE SIMPLIFICATION PROGRAMME

Based on the New Approach, rules relating to the safety and performance of medical devices were harmonised in the EU in the nineties, beginning in 1990 with Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to **active implantable medical devices** and later followed in 1993 by Council Directive 93/42/EEC of 14 June 1993 concerning **medical devices** and in 1998 by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on ***in vitro* diagnostic medical devices**.

These three legal texts form the core legal framework. Their aim is to ensure the **functioning of the internal market** and a **high level of protection of human health and safety**. They have been supplemented over time by six modifying or implementing Directives, including the last technical revision brought about by Directive 2007/47/EC of the European Parliament and of the Council.

The Commission, in its Communication to the European Parliament and Council, "Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment", COM(2005) 535, committed itself **to recast (in a Regulation) Directive 90/385/EEC (on implantable medical devices), 93/42/EEC (general framework) and Directives 2000/70/EC and 2001/104/EC (on blood derivatives).**

However, since 2005, a number of drivers have come into play that necessitates **not only a simplification of these four texts but also a strengthening of the whole legal framework.**

2. OPPORTUNITIES TO STRENGTHEN THE FRAMEWORK

(a) Emerging Weaknesses

The key elements to the framework are Notified Bodies, Clinical Evaluation, Vigilance, Market Surveillance, and Transparency. Experience indicates that the current system does not offer as high a level of protection of health as possible:

– **Notified Bodies**: Since the adoption of the main Directive on medical devices in 1993 the EU has expanded from 12 to 27 Member States. This enlargement has seen the number of Notified Bodies grow to nearly 80 in number. The original system of oversight needs to react accordingly. In particular to ensure:

- Consistent designation and monitoring of Notified Bodies;
- Uniform levels of safety and in particular in the field of **clinical evaluation;**
- Harmonised interpretation of the tasks of a notified body;

- Appropriate transparency to the Member States, other Notified Bodies, the Commission, and the citizen.

– **Vigilance:** Vigilance data, that is data on serious incidents involving medical devices, is key to providing early warning of safety issues. Compared to similar markets, the EU has a low overall reported rate of incidents. Furthermore, reporting rates per capita vary across the EU. As it is unlikely that medical devices are 'safer' if used within the EU, and, within the EU, even safer in some Member States, it is clear that the vigilance system and reporting of vigilance issues need to be improved. When a vigilance issue is identified stronger provisions are needed to ensure a common reaction in the market of the whole Community.

– **Market Surveillance:** CE marked medical devices are free to move within all Member States. However not all Member States have the necessary resources to survey their market. And nor, due to competing national priorities, is there always the most desirable cooperation between Member States to help fill this gap in resources. Add to this a poor utilisation of the current legal tools and you have a situation that can lead to internal market fragmentation and a possible threat to public health. Here too clarified and stronger provisions are needed to ensure a common reaction in the market of the whole Community.

– **Transparency:** There is a general lack of basic information, such as what medical devices are on the market and to what extent they have been checked. There is also insufficient formal exchange of information between the Competent Authorities. It is a basic expectation that there should be a transparent system whereby citizens can be confident in the safety of medical devices.

(b) New and emerging technologies

New and emerging technologies have challenged the current framework, highlighting gaps or pointing to potential loopholes including the scarcity of expertise needed to independently assess such technologies. The framework needs to fill these gaps and be made more robust to future technologies.

One such technology which the current legislation needs to be broadened to cover is medical devices that consist of, or which incorporate, non-viable human cells and tissues. This one example alone highlights the **scarcity of expertise** to assess such products both at a national and at an EU level.

(c) Global Market

The **medical devices market is a global one**, with our major trading partners increasingly aligning their legislation to the Global Harmonisation Task Force for Medical Devices (GHTF) model. To keep European industry competitive, the European legislation also needs to further converge on this model.

(d) Greater Simplification and Harmonisation

Currently, with three main Directives and six modifying or implementing Directives, the framework has been criticised as being **too fragmented and difficult to follow**. This situation is further compounded by **national variation** including different decisions on whether a product is a medicinal product or a medical device, differences in the classification of the same type of devices and different registration requirements. This variation threatens not only the smooth functioning of the internal market, but could also threaten the health and safety of patients, healthcare professionals and other persons.

3. OPTIONS TO ADDRESS THE ISSUES

The Commission intends to undertake a more fundamental exercise and **recast the entire framework** for medical devices (active implantable medical devices, medical devices and in vitro diagnostic medical devices) **in order to address the above mentioned issues** and to **anticipate the challenges** in front of us. Looking to 5, 10 or even 15 years ahead, the Commission intends to make **the model better and more robust to the technical and more generally public health challenges ahead**.

This **would not lead to the rejection of the New Approach in this sector**. The rules would be reinforced and adapted to new challenges within the current legislative structure. This model has proven to be adept in allowing innovation in a sector characterized by a broad diversity of products.

Stakeholders are invited to comment on the **main issues** such as:

– an extension of the scope of the Directives, in particular, to include medical devices consisting of non-viable human cells and/or tissues and/or their derivatives and devices incorporating such cells and/or tissues and/or their derivatives with an ancillary action to that of the medical device;

– a reinforcement of the essential requirements and a strengthening of the evaluation procedures for the highest risk category products;

– a consolidation of expertise, in particular through the creation of a Medical Device Committee inside the European Medicines Agency (EMEA), the competence of the latter being extended to cover not only medicinal products but also medical devices;

– a system of vigilance and market surveillance that is more effective and more coordinated between Member States;

– a specific update following the revision of the New Approach;

– an alignment with international regulatory principles.

4. RESPONSES

The responses to this consultation are going to be carefully studied by the Commission services to assess:

- to what extent the Medical Devices Directives can be **improved**; and
- the **socio-economic** impact of the changes envisaged and, in particular, the impact on the **protection of health and safety** of patients, healthcare professionals or, where applicable, other users, on **the functioning of the internal market** and on the **competitiveness** of industry including, in particular, SMEs.

Therefore to the greatest extent possible, respondents should include in their answers data corresponding to these different aspects (social and economic data) supported, where possible, by an evaluation of actual or estimated costs (expressed in figures such as cost per device, cost per manufacturer, cost per national authority, cost per hour, cost per man-day etc.), and by other quantitative relevant figures.

Particular emphasis on the impacts, costs and savings to SMEs would be welcome.

QUESTIONNAIRE

1. Scope

Today the legislative framework for medical devices in Europe comprises three main Directives and the six implementing or modifying Directives. The three main Directives cover three main device groups: active implantable medical devices, medical devices and *in vitro* diagnostic medical devices. However, the reason for having three is more historical than technical or legal. While recognising certain specificities in relation to *in vitro* diagnostic medical devices there is the possibility to **consolidate all existing harmonisation measures** on medical devices into a **single text**.

Item 1 Legal simplification: Do you see any positive or negative impacts of merging the nine texts into one legal text? Can you give an estimate of the costs of those impacts both in absolute terms and in terms of a breakdown of those cost components (e.g. per year or in man days)?

Specifically concerning in vitro diagnostic medical devices, Study Group 1 of the Global Harmonisation Task Force for medical devices (GHTF) is proposing a risk-based classification system for in vitro diagnostic medical devices. Such a classification system has the advantages of being in line with the medical devices Directive 93/42/EEC and seems to be robust to technological change.

Item 2 Risk-based classification: In your opinion is such a risk-based classification system more desirable than the current European List system? Are you aware of any consequences for the protection of public health? Can you give an estimation of the costs or savings that would result from a change-over to this GHTF classification system?

Further to the current scope of the medical device Directives some medical devices are not regulated at a European level, namely those defined as **medical devices consisting exclusively of non viable human cells and/or tissues and/or their derivatives and medical devices incorporating such cells and/or tissues and/or their derivatives with an ancillary action to that of the medical device**. As the need to cover these products has been recognised by the European Institutions, the scope of the Directives could be expanded to include such medical devices in order to cover the regulatory gap that exists at the Community level with the adoption of EC Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

Item 3: To your knowledge, are these the only medical devices currently not regulated at an EU level? Can you indicate others? Is the definition as given above accurate to describe these medical devices? Can you suggest an alternative definition?

Some **implantable** or **invasive** products are on the market **which are not specifically regulated at the EU level**: they are neither medicinal products nor medical devices, as they do not have a medical purpose, and they are not covered by the definition of cosmetics, as they are implanted or injected. Some examples are cosmetic lip implants, cosmetic wrinkle fillers, tattoo needles and equipment, implanted 'identification chips' and contact lenses for cosmetic purposes.

However, these products can present the **same risks** as medical devices. This is why it could be appropriate to consider them as **'quasi medical devices'** and to include them under the umbrella of the medical devices regime. The issue of machines used for aesthetic purposes could also be tackled in this context.

Item 4: In your opinion is it necessary to ensure full protection of public health to regulate these products as 'quasi medical devices'? Assuming that a Notified Body assessment would be necessary for these implantable or invasive 'quasi medical devices', can you estimate the impact in terms of cost for each of the three following options (per product, per year, man hours)?

The delimitation of these products can be done in different ways:

Option 1: Regulate as 'quasi medical devices' all implantable or invasive products which are not covered by another specific Community legislative regime (medicinal products, cosmetics, medical devices);

Option 2: Regulate as 'quasi medical devices' those products which belong to a category of products which also includes products with a medical purpose (for example, cosmetic contact lenses, as there are some contact lenses intended to be used for medical purposes, cosmetic wrinkle fillers, as there are some wrinkle fillers intended to be used for medical purposes, etc.);

Option 3: Regulate as 'quasi medical devices' those products that would be listed exhaustively in an Annex to the future Medical Devices Legislation.

What would be the socio-economic impact of these options?

Can you suggest any other options?

2. Specific Update following the revision of the New Approach

The medical device legislation comes under the overall umbrella legislative framework for industrial products called the 'New Approach'. The revision of this New Approach is nearly finalised. The revision of the medical devices regime will go beyond the aspects modified by the revision of the new Approach in order to reflect the public health nature of the sector. But the new regime for medical devices will have to be set up **in the light of the revision of the New Approach**.

Item 5:

– Which aspects of the revision of the New Approach do you consider of particular relevance to the medical devices sector, and why?

– It could be necessary to deviate, modify or add requirements, as compared to the New Approach, to reflect the peculiarities of the medical devices sector, as unlike other industrial products, medical devices have a direct effect on the health and safety of citizens. What deviations, modifications or additional requirements would you recommend, and why?

3. Evaluation Procedures

a) Essential Requirements

i. Adaptation/reinforcement of the essential requirements – creation of new essential requirements

Adaptation of the essential requirements could be necessary should the devices referred to in items 3 and 4 (non viable human tissues and/or cells and/or their derivatives and 'quasi medical devices') be included into the Medical Devices Legislation. Also, it could be that certain essential requirements **are missing** or should be **reinforced**.

More generally, it should be checked if the current requirements are **sufficiently robust** to innovative technologies and practices (for example, nano-technology, non-viable animal tissues or their derivatives, genetic testing and advancements in information technology).

Moreover, it could be necessary to create **new essential requirements** in order, for example, to fight against counterfeiting (unique device identification, such as bar-coding, for example) and to assure a safe distribution.

Item 6: In your opinion what changes are needed to the essential requirements:

a) in general?

b) for non viable tissues and/or cells and/or their derivatives?

c) for 'quasi medical devices'?

d) to make medical devices more robust to technology change?

What new essential requirements could be needed and why?

Please also estimate the socio-economic impact of the changes in each case.

ii. More mandatory rules

The essential requirements for medical devices are set out in the Directives, but are deliberately technology neutral and do not enter into the technical details. These technical details are set out in harmonised European standards. However these standards are voluntary and there is room for differing interpretations.

Moreover, even in cases where there is scientific agreement that a certain device, method or material is not safe, the Directives do not provide a tool to address such issues efficiently at a Community level. The only tool available to Member States in such cases is the Safeguard Clause, which is not always appropriate or used. In order to solve this type of problem, Member States often seem to use guidance, alerts etc., which effectively leads to a more fragmented market.

To ensure the protection of health and to the eliminate fragmentation of the internal market, the possibility should be examined to allow more precision or detail to be given **in order to specify the essential requirements** in relation to certain devices, methods or materials, in a mandatory way, without compromising the existing role of standardisation. Such requirements could be termed **harmonised specific requirements**

Item 7: Can you cite instances of Member States introducing their own national specific device, method or material requirements? Can you give an estimate of the costs arising from these differing specific device requirements? What would be the socio-economic impacts of the introduction of 'harmonised specific requirements'?

b) <u>The Evaluation Process</u>

i. Notified Bodies

The job of **designation** and **monitoring** of Notified Bodies is the responsibility of individual Member States, with each Member State deciding on the appropriate

method and resources necessary to do this task. Voluntary coordination between Member States ensures consistency.

Since the adoption of the main Directive on medical devices in 1993 the EU has expanded from 12 to 27 Member States with upwards of 80 Notified Bodies. To continue to ensure consistency the original system of oversight needs to react accordingly. With potentially 27 differing designation and monitoring regimes it could be argued that not all Notified Bodies are equally designated or monitored, particularly when there is a lack of **transparency** into the competence, performance and activities of Notified Bodies to counter-act this argument.

This creates the situation where the guarantee that the same level of assessment of safety of medical devices being offered throughout the Community can be questioned.

Item 8: The Commission intends to make some proposals concerning the functioning and the activities of the Notified Bodies, some of which could be cumulative. Furthermore two options could be put forward to strengthen the system. What is your opinion on each proposal and option and what would be an estimate of the impacts and costs involved?

Proposal 1

To increase transparency into the activities of Notified Bodies (e.g. obligation for the Notified Body to publish annual reports);

Proposal 2

To develop a system of improved information exchange from Notified Bodies to Competent Authorities;

Proposal 3

To ensure an improved cooperation between Competent Authorities with regard to the activities of Notified Bodies;

Proposal 4

To impose the application by the Member States of sanctions and penalties where a Notified Body fails to act properly;

Proposal 5

To introduce measures to stop 'forum shopping' by manufacturers. Forum shopping is the informal name given to the practice adopted by some manufacturers of getting their products reviewed by the Notified Body thought most likely to provide a favourable opinion;

Proposal 6

To create an automatic link between accepted Safeguard Clauses and the withdrawal of certification for the related medical devices.

The above proposals could be coupled with one or both of the following options:

Option 1

The reinforcement of controls on the nomination (including setting out and defining the role of accreditation) and monitoring of the Notified Bodies by Member States;

Option 2

A centralised system of final designation and of control of monitoring by the Commission with the assistance of experts.

ii. Highest risk category medical devices

Currently there is no systematic public authority input or say in the approval of the highest risk category medical devices, such as coronary stents, pacemakers, HIV test kits or diagnostics to accompanying advanced therapy medicinal products, **before they are placed on the market**. However, the European Medicines Agency (EMEA) or a national medicines authority are involved in the evaluation of some devices - those that are combined with an ancillary medicinal product - and EMEA is always involved in the assessment of medical devices combined with ancillary human blood derivatives.

The question arises as to whether there should be either a *de jure* or a *de facto* pre-market authorisation of these highest risk category medical devices.

The competence of EMEA could be extended, in particular to the involvement in the evaluation of the **highest risk category devices**, thus introducing a 'public health' component into the evaluation process, with the question being still open as to the involvement of Notified Bodies in the process.

EMEA has over 10 years of experience in the protection and promotion of public health, through the evaluation and supervision of medicines for human and veterinary use in Europe. EMEA already works with Member States' national authorities, many of whom have dual responsibility for both medicinal products and medical devices. EMEA therefore already has the structures and networks in place to pool scientific and technical expertise to guarantee a harmonised high level of evaluation.

It could therefore be appropriate to adapt the existing structure of EMEA. Specific, multidisciplinary expertise would need to be brought on board to **create a specific Medical Device component of EMEA**, on an **equal footing** with medicinal products. Coupled with this, and, in a similar way to medicinal products, it could also be appropriate to **create a specific Committee in EMEA on Medical Devices** (COMD).

Item 9: What are the social and economic advantages and disadvantages of extending the role of EMEA in the medical devices legislative framework? If possible, and where appropriate, please express these social and economic advantages and disadvantages in terms of cost.

What in your opinion is an appropriate timeframe for the assessment and approval of a highest risk category device?

Item 10: If EMEA were to participate in the evaluation of highest risk category devices, which products should these be (e.g. medical devices consisting exclusively of non viable human cells and/or tissues and/or their derivatives and medical devices incorporating such cells and/or tissues and/or their derivatives with an ancillary action to that of the medical device, and **certain** products from the following categories: class III medical devices, devices using nano-materials, in vitro diagnostic and active implantable medical devices)?

As the EMEA expertise and approval process is already foreseen for 'viable' human tissues (under Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004), it would seem logical to also submit 'non-viable' tissues to approval via the same expertise and process. What in your opinion would be the social and economic impacts if this was the case?

Item 11: Two basic considerations arise with an expanded role of EMEA in the evaluation of the highest risk category medical devices: (i) in what way does a file get submitted to EMEA for an opinion and (ii) What is the final decision making process?

On both aspects some solutions can be proposed. Which ones, in your opinion, are the best ones and why? Can you suggest other modalities in order to involve of EMEA in the evaluation of the highest risk category devices and to take into account the opinions delivered by EMEA?

(i) in what way does a file get submitted to EMEA for an opinion?

Option 1.

No Notified body involvement, thus obliging direct submission of manufacturers' files related to highest risk category devices to EMEA for an opinion;

Option 2.

A variation of option 1. Obliging manufacturers to directly submit their files related to highest risk category devices to EMEA, and EMEA then selects a Notified Body to act as a 'rapporteur'. The Notified Body 'rapporteur' then assesses the file and sends its recommendation to EMEA for a final opinion;

Option 3.

Maintain the Notified Body responsibility for the overall assessment of the files as it is at present, but oblige Notified Bodies to send their preliminary reports concerning highest risk category medical devices to EMEA for an opinion;

Option 4.

A variation of option 3. Keep the Notified Body responsibility for the overall assessment of the files but instead of a systematic assessment of the preliminary report by EMEA, oblige Notified Bodies to notify EMEA of all applications for evaluation of highest risk category devices and allow EMEA, on a public health interest basis, to select those evaluation reports on which they will give an opinion.

(ii) What is the final decision making process?

Two possibilities can be foreseen:

Possibility 1: For options 1 or 2 above, i.e. an EMEA opinion rather than a Notified Body certificate, the normal decision making process would be a Commission market authorisation based on a Comitology decision.

Possibility 2: For options 3 or 4 above, i.e. maintain overall responsibility with the Notified Body, then the system could continue as it is now, with the Notified Body issuing its certificate, but only if it had received a positive opinion from EMEA.

iii. Devices which do not belong to the highest risk category

To contribute to the **monitoring** of the conformity assessment by Notified Bodies of devices **which do not belong to the highest risk category**, the EMEA Medical Devices Committee could also have the possibility to examine any matter concerning a specific device placed on the market or to review any data relating to a specific family of medical devices.

Item 12: Do you see any reason why the EMEA Medical Devices Committee should not also have the possibility to have access to all evaluation reports of the Notified Bodies in order to establish and monitor a high level of evaluation and to require corrective action where needed?

4. Vigilance

Vigilance issues are recorded by e-mail or centrally in the European database for medical devices, EUDAMED. The wide variation of reported vigilance issues points to a **significant under-reporting** of incidents within the EU.

When issues do take place, it should be ensured that the same common reaction takes place in all Member States; however, experience has shown that **not all Member States always react in the same way**.

Item 13: One or more proposals to improve the vigilance system could be foreseen to be appropriate. In each case can you give an estimate of the socio-economic impact of the particular proposal?

Proposal 1

Establish an obligation for the medical institutions and healthcare professionals to report incidents and to invite patients to do the same, to introduce timelines for reporting and corrective actions, to give certain publicity to the corrective actions of the manufacturer;

Proposal 2

Create an obligation for the Notified Body to periodically review the manufacturer's vigilance system;

Proposal 3

Mandate EMEA to coordinate vigilance reports and to detect signals;

Proposal 4

Allow the Commission to impose restrictive measures, on the basis of the opinion of the Medical Device Committee in EMEA.

Proposal 5

Also, remembering that the medical device market is very much a global one, should there be provision for exchange of information on incidents and corrective measures at an international level? This happens now voluntarily through GHTF but could be strengthened.

5. Market Surveillance

Member States' control of the market can **vary significantly** depending on the availability of adequate resources. A counter-balance to this lack of resources is efficient and effective cooperation between the Member States. However experience has shown that this cooperation is not always optimal.

This situation is not helped by **confusion** on how to operate the **current market surveillance tools already contained within the Directives**, not least due to the current provisions being unclear and appearing in different and apparently disjointed sections of the Directives.

Item 14: In order to reinforce market surveillance, it could be appropriate:

– to have a central European registration system for devices;

– to redraft and rationalise the rules on market surveillance;

– to strengthen the provisions related to the Commission on coordination; and,

– in cases where the Commission has to take a decision, to have the possibility to ask for a scientific opinion of the Medical Device Committee in EMEA.

Do you see any problems with these measures to increase the integrity of market surveillance?

Can you suggest other improvements?

6. Borderline Cases

Innovators need to be certain as to which regulatory regime their products will fall. Due to the fact that most borderline cases involve medical devices and medicinal products, a **strong dual expertise** in borderline cases in both areas becomes more and more necessary. It could be useful to provide that manufacturers could go directly to EMEA for an **early opinion** prior to development of their product. This opinion should be delivered in a defined timeline; Notified Bodies, Competent Authorities and the Commission could likewise seek an opinion.

Item 15: The Medical Device Committee in EMEA could provide a joint opinion together with the Committee for Medicinal Products for Human Use (CHMP) on the appropriate qualification of a product.

It can also be envisaged that the Committee on Medical Devices in EMEA could provide an opinion on the classification of a medical device. Or indeed that EMEA could give scientific opinions or advice on other technical matters related to medical devices.

What would be the health or economic impact of such a system in your view?

7. GHTF

The medical devices market is a global one, with our major trading partners increasingly aligning their legislation to the Global Harmonisation Task Force for Medical Devices (GHTF) model. **To keep European industry competitive, the European legislation also needs to further converge on this model.**

Item 16: It would be appropriate to evaluate the GHTF guidance documents and carry over as much as possible into the European framework.

Can you (roughly) estimate the costs stemming from international regulatory divergences? What are the positive and negative impacts of Europe harmonising to the GHTF global regulatory model?

To what extent should European legislation reflect the GHTF global model:

Fully?

Only where possible? Please explain which areas are possible and why?

Not at all? Please explain why?

Which GHTF guidance documents would you recommend to be carried over into European legislation?

If fully aligned, can you estimate the savings this would bring about for European businesses?

What would be the added value in terms of protection of public health?

8. Imports, Exports and Counterfeiting

Imports: All medical devices sold in the EU must be CE marked. This means that imported products are subject to the same level of checking and control by Member States' authorities and Notified Bodies as domestic European products.

This requirement for equal treatment of imported and domestic products has been challenged over the years, particularly in respect to medical devices manufactured in emerging economies. Claims have been made that Notified Bodies do not check foreign manufacturers with the same rigour and due diligence as they do for EU manufacturers. In the same vein, concerns have been voiced that authorities do not actively and thoroughly follow up alleged claims of non-conforming and unsafe imported medical devices, particularly custom-made and lower risk, class I, imported medical devices.

Item 17: Can you suggest any specific proposals to strengthen the European system against the criticism of having un-equal checking and control of imported versus domestic medical devices?

Exports: Under the current system, it can be argued that the EU has **a double standard**. While devices that are placed on the Community market are subject to control, unless the country of import themselves have regulations, neither the manufacturing process nor the manufacturers of "export medical devices" are regulated. This would seem at odds with the idea of Europe as a centre of safety, excellence and innovation in medical devices.

Item 18: For those cases where there is **no legal requirements in the importing country**, a separate export certificate regime could be developing based upon the Directives, say requiring medical devices for export to be treated in the same way as medical devices for the Community market (affixed with CE marking) or requiring the manufacturer to have a quality management system (Device GMP). Please give your evaluation of such proposals in terms of social and economic impacts.

Counterfeiting: The Commission is considering introducing traceability requirements into the essential requirements for medical devices to help battle against counterfeiting [see section 3(a)(i) above]. But other measures outside the essential requirements might also be appropriate.

Item 19: Can you suggest appropriate measures within a future legal framework for medical devices that could help battle against the counterfeiting of medical devices?

9. Simplification

Currently, with three main Directives and six modifying or implementing Directives, the legal framework for medical devices has been criticised as being too fragmented and **difficult to follow**, particularly for SMEs or third country manufacturers and trade partners.

Furthermore and probably more importantly, uniform implementation of the Directives has been hampered by **national variation** concerning, for example, the interpretation of the definition of a medical device and of the rules for classification and the registration procedures. This variation threatens not only the smooth functioning of the internal market, but could also threaten the health and safety of patients, healthcare professionals and other persons.

For these reasons, some parts of the text should also be **restructured** and **clarified**. Furthermore, it could be useful to examine **if it is legally possible to use a Regulation** rather than a Directive to ensure uniformity, or to use **a combination** of a Regulation and a Directive (if a single regulation is not legally possible).

Item 20: Which elements in the Medical Devices Directives have given rise to particular legal uncertainty in regard to their application? Did this increase administrative burden, e.g. costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g. by assessing the necessary man-hours? How can these costs be reduced without compromising the safety of medical devices placed on the market?

Item 21: Would it be preferable to regulate medical devices by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? What would be the socio-economic impact of this option?

The variety of conformity assessment modules (Annexes) in the Directives are difficult to follow, except for the most experienced and expert regulatory professional. Since the Directives were first introduced, industrial and international regulatory practice in device quality management has moved on. Device GMP, as described in quality management system standard EN ISO 13485:2003 and related standards, has replaced EN 46001, EN 46002 and EN 46003 (the European standards that spoke to the various modules). It could be the case that Europe **is retaining compliance routes that are out of step with the industrial state of the art**.

Item 22: It could be envisaged to collapse all the quality system conformity assessment modules into one module, analogous to the current Annex II module in Directive 93/42/EEC concerning medical devices. Would this be a simplification of the system? What would be the benefits in terms of administrative burden and cost?

If certain conformity options are to be retained, which ones and why? What are the convincing social and economic arguments to keep them? Can you estimate the negative impact if they are phased out?

Any comments and information on this public consultation should be submitted by mail, fax or e-mail by Wednesday evening, 2nd July 2008, at the latest to:

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Respondents should indicate the interests that they represent (i.e. whether they are a national authority, patient, health professional, consumer, notified body, industry, trade association, academia, etc.).

If they are a company, the approximate size (turnover, employees) and the main market (product market and geographical market) should be indicated.

Submissions will be published on the "medical devices" website of the European Commission. Respondents should indicate whether they wish the Commission to treat their submission as confidential by indicating the word "confidential" on the first page of the contribution.